Claim Rejections – 35 U.S.C. § 103

On pages 1-4 of the Office Action, the Examiner rejected claims 1, 5, 7 and 9 under 35 U.S.C. § 103(a) as being unpatentable over Rabiner in view of Francis.

Applicant has carefully considered the Examiner's comments and cited art, and respectfully submits that claims 1, 5, 7 and 9 are patentably distinct from the cited art for at least the following reasons.

Claims 1 and 9 recite, among other features, a catheter for insertion into the human body including one or more ultrasonic transducers and a surgical instrument to be operated from the outside. The surgical instrument comprises a needle for the introduction of a substance or for the extraction of tissue samples. The catheter comprises at least two parts shaped like hemicylindrical shells and having circular arc cross sections, as well as a rod is inserted between those two parts. The two parts are surrounded by an outer tube. The end of the rod is provided with an ultrasonic transducer. The outer surface of one of the parts is provided with a longitudinal groove for the insertion of the surgical instrument. The longitudinal groove is shaped such that the surgical tool, including the needle, can be inserted from the outside of the human body into the human body via the longitudinal groove. The parts removably engage

each other – i.e., they have abutting surfaces shaped so that they can be locked relative to one another – and are kept together by the surrounding tube when the catheter is assembled. The abutment of the parts is depicted in Fig. 2 of the application by means of the black line of the longitudinal seam formed where the two parts (elements 2 and 3) meet. The parts are capable of being removed from the outer tube and disengaged from each other.

The Examiner contends that "Rabiner discloses a catheter with at least two circular or partially circular cross sectional parts 109, 109, Fig. 3F where a rod 6 is inserted between the parts and at the end is provided with an ultrasonic transducer 22, 23. The semi-circular parts are surrounded by an outer tube 108, Fig. 3B." Rabiner actually discloses a shielded ultrasonic probe for tissue ablation. The entire rod 6 is an ultrasonic probe (col. 12, ll. 19-23), and the elements the Examiner calls "an ultrasonic transducer 22, 23" are the terminal segment 22 and tip 23 of the probe (col. 11, ll. 64-65). The semicircular parts 109 and the outer tube 108 are elements of two mutually exclusive dampening sheath configurations for the ultrasonic probe (col. 12, ll. 19-21). There is no teaching or suggestion that the sheath 108 of one embodiment may interact in any way with the sheath 109 of the other embodiment.

Therefore, Rabiner fails to disclose that the catheter includes one or more ultrasonic transducers *and* a surgical instrument to be operated from the outside. Rabiner fails to disclose that the two parts are surrounded by an outer tube. Rabiner fails to disclose a rod element that is distinct from an ultrasonic transducer element.

The Examiner goes on to state that "Rabiner discloses that the parts 109, 109 can be locked relative to one another 113, and that the rod 6 with the ultrasonic transducer can be rotated relative to the completely or partially circular parts C4 L54-56." However, this teaching, if true, does not encompass the language of claim 1. Claim 1 does not merely recite that the parts can be locked relative to one another. Claim 1 requires that the partially circular parts have abutting surfaces shaped so that they can be locked relative to one another and a seam is formed between the parts. The parts 109 of Rabiner do not abut, but rather a connector element 113 is transposed between the two parts, creating a gap that separates them, as opposed to a seam where they meet.

Therefore, Rabiner fails to disclose that the partially circulating parts having abutting surfaces shaped so that they can be locked relative to one another.

The Examiner contends that "[t]he surface of at least one of the parts 109 is provided with a longitudinal groove for the

insertion of a surgical instrument col. 9, lines 1-11, C12 lines 46-50. The surgical instrument of Rabiner C8L65-67 is a needle and the longitudinal groove in the sheath is shaped such that the needle extends immediately below and parallel to the outer tube, see Figs. 6-7." Rabiner actually teaches that the sheath may provide at least one aspiration channel to remove ablated tissue and fluids (col. 9, ll. 1-11). The aspiration channel structure is patentably distinct from the groove contemplated by instant invention, since it is adapted for the passage of fluids (col. 11, ll. 58-63), and not for the passage of a solid object, such as a surgical tool. Note that where the groove of the instant invention gently slopes at the surface of the hemicylindrical part in order to accommodate a flexible needle, but the aspiration channels of Rabiner (Fig. 6) end abruptly and would not accommodate needle insertion. Neither "Rabiner C8L65-67" nor "Figs. 6-7" disclose a needle or equivalent structure. At column 8, line 65 through column 9, line 1, Rabiner provides that the aspiration channel can be connected to a vacuum device so that tissue debris created by the probe's operation can be removed by suction. Figures 6 and 7 show longitudinal and transverse cross-sectional views of the ultrasonic probe. See col. 6, ll. 12-18. The word "needle" does not appear in the Rabiner disclosure.

Therefore, Rabiner fails to disclose that the circular or semicircular parts are provided with a longitudinal groove for the insertion of the surgical instrument. Rabiner fails to disclose that the surgical instrument comprise a needle for the introduction of a substance or for the extraction of tissue samples. Rabiner therefore also fails to disclose that the surgical instrument is operated from the outside, and that the longitudinal groove is shaped to accommodate it.

The Examiner does not attempt to show that Rabiner teaches that the completely or partially circular parts removably engage each other and are kept together by the outer tube when the catheter is assembled, and that the parts are capable of being removed from the outer tube and disengaged from each other for sterilization/disinfecting purposes. Instead, the Examiner states the following:

> "Francis, in the analogous art, teaches two housing pieces 110a, 110b removably engaged and locked relative to one another, Fig. 2. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the connection 113 removably engageable for easier disinfecting or sterilization to make the unit reusable to lower procedural expenses. Thus, since it is considered desirable to remove and sterilize the sheath it would be obvious to make the two parts 109, 109 removably engageable with one another as taught by Francis to allow for easier removal around the probe and other parts of the ultrasonic device. Thus also, once the parts were separate, it would be inherent that the outer tube 108 surrounding the parts would keep together the parts."

However, the housing pieces 110a and 110b of Francis bear no structural or functional resemblance to the completely or

partially circular parts of the claimed invention. First, housing pieces 110a and 110b do not have circular arc cross sections. See, e.g. Fig. 4. Second, they do not enclose a rod that is provided at the end with an ultrasonic transducer. Rather, they support an eyepiece unit and illuminator connector of an endoscope (col. 4, ll. 19-28). Furthermore, there is no need to disassemble the sheath of Rabiner for the purpose of making the unit reusable – the unit is already easily sterilized (col. 13, ll. 62-65). The sheath need not be broken into two halves because, of necessity, there is ample space between the vibrating probe and the inside of the sheath. The structural integrity of the sheaths disclosed by Rabiner is essential to their cavitation energy shielding capability, and would be adversely affected by a change to their integral nature (col. 13, ll. 42-62). Finally, the Examiner asserts that it would be inherent for the outer tube 108 to keep the parts together once they were separated. This allegedly inherent condition contradicts the claimed invention, wherein the outer tube is *removed* when the parts are separated. Moreover, this condition cannot be inherent because, as discussed above, the outer tube is not used in conjunction with the two-part, hemicylindrical sheath disclosed in Rabiner.

Therefore, Francis does not cure the deficiencies of Rabiner with regard to the removable engagement feature of the

partially circular parts of the instant invention. As explained above Francis does not teach the claimed feature, the hypothetical combination of Francis and Rabiner set forth by the examiner does not encompass the claim language, and this hypothetical combination would destroy the functionality of the ablation probe taught by Rabiner. The motivation to combine the two references is inapplicable, because the device of Rabiner is already easily cleaned and reused by virtue of the fact that it is a completely different surgical tool from that of the instant application. The recitations of intended use within the claims correspond to explicit structural recitations within the claims, and result in numerous structural differences as discussed at length in this Response. Neither the tissue ablation device of Rabiner nor the laparoscope of Francis is capable of performing the intended uses of the present catheter for insertion into the human body.

Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the claim rejections based upon § 103(a) with regard to the pending claims.

A formal notice of allowance is respectfully requested.

No fees are required in connection with the filing of this Communication. However, the Commissioner is hereby authorized to charge any additional fees required in connection with the filing of this Communication to Deposit Account No. 03-3125.

Respectfully submitted,

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/s Tonia A. Sayour/ November 22, 2011
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